

## REMARKS

The pending Office Action addresses claims 1-19, 21-24, 27-40, and 65-74, however claims 5, 11, and 27-33 are withdrawn from consideration. Claims 24, 69, and 72 are objected to, and claims 1-4, 6-10, 12-23, 34-40, 65-68, 70, 71, 73, and 74 stand rejected. Reconsideration and allowance are respectfully requested in view of the following remarks.

### ***Rejections Pursuant to 35 U.S.C. §102***

#### *U.S. Patent No. 6,447,512 of Landry*

The Examiner continues to reject claims 1-4, 6-10, 12-19, 21-23, 34-40, 65-68, 70, 71, and 74 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,447,512 of Landry et al. In Applicant's previous response, Applicant argued that Landry does not teach or even suggest a guide device for use with a spinal fixation element that includes an elongate shaft having a proximal end that is positioned at an angle with respect to a distal end of the shaft, as required by independent claims 1, 35, 65, and 74. In response, the Examiner argues that:

The new limitations: "positioned at an angle with respect to the distal end of the shaft" have been examined, however, the proximal end (174) of the shaft (172), as interpreted by the Examiner, still read on the Landry et al reference. As shown in Figure 22, the proximal end (174) of the shaft (172) being positioned at a zero degree angle with respect to the distal end (168) of the shaft.

The Examiner goes on to suggest that, in order to overcome the rejection, Applicant should recite that the shaft is "bended or something alike."

Independent claims 1, 35, 65, and 74 do recite that the shaft is bent, as the claims require that the proximal portion extends at an *angle* relative to the distal portion. The term "angle" is defined as "the space within two lines or three or more planes *diverging* from a common point, or within two planes diverging from a common line." (www.dictionary.com, *emphasis added*). This definition necessarily excludes a straight line, as a straight line (or two lines extending at zero degrees) does not include any portion that diverges from a common point. The *straight* shaft of Landry therefore cannot include a proximal end that is positioned at an *angle* with respect to the distal end. Accordingly, independent claims 1, 35, 65, and 74, as well as claims 2-4, 6-10, 12-19, 21-23, 34, 36-

40, 66-68, 70, and 71 which depend therefrom, distinguish over Landry and represent allowable subject matter.

U.S. Patent No. 6,113,602 of Sand

The Examiner also continues to reject claim 73 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,113,602 of Sand. Applicants disagree with the Examiner's rejection for the same reasons discussed above. Sand, like Landry, does not teach or even suggest an elongate shaft having a proximal portion that extends at an *angle* relative to a distal portion. Rather, Sand teaches an instrument guide having proximal and distal regions that are linearly aligned with one another, i.e., that are straight. Accordingly, independent claim 73 distinguishes over Sand and represents allowable subject matter.

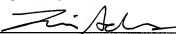
**Conclusion**

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants is such communication is deemed to expedite the prosecution of this application.

Date: March 21, 2007

Nutter McClennen & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210  
Tel: (617)439-2550  
Fax: (617)310-9550

Respectfully submitted,

  
\_\_\_\_\_  
Lisa Adams, Reg. No. 44,238  
Attorney for Applicant(s)

**PENDING CLAIMS**

1. (Previously Presented) A guide device for use with a spinal fixation element having at least one pair of thru bores formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end, the proximal end of the shaft being positioned at an angle with respect to the distal end of the shaft;

a guide member coupled to the distal end of the elongate shaft and including first and second pathways at least partially in communication with one another and extending therethrough in a fixed relation to one another, the distal end of the elongate shaft being offset from the first and second pathways; and

at least one alignment element positioned distal of the guide member, the at least one alignment element being adapted to interact with a spinal fixation element to position the guide member with respect to the spinal fixation element such that the first and second pathways in the guide member are aligned with a pair of corresponding thru bores formed in the spinal fixation element.

2. (Original) The guide device of claim 1, wherein the at least one alignment element comprises at least one tab that extends distally from the guide member.

3. (Previously Presented) The guide device of claim 2, wherein the at least one alignment element is adapted to rest against an edge of a spinal fixation plate such that the alignment element does not extend into any portion of the spinal fixation plate.

4. (Previously Presented) The guide device of claim 2, wherein the at least one alignment element is adapted to rest against an edge of a spinal fixation plate and to provide a sliding interference fit with the spinal fixation plate.

5. (Withdrawn) The guide device of claim 2, wherein the at least one tab comprises opposed first and second tabs that extend distally from the guide member, the first and second tabs being movable between an open position, and a closed position wherein the tabs are adapted to engage opposed edges of a spinal fixation element.

6. (Previously Presented) The guide device of claim 2, wherein the at least one tab comprises first and second opposed alignment tabs that extend from opposed outer edges of the guide member at positions that are substantially between the first and second pathways.
7. (Previously Presented) The guide device of claim 2, wherein the at least one tab comprises first and second opposed alignment tabs that extend from opposed outer edges of opposed ends of the guide member such that the first and second pathways are positioned between the first and second alignment tabs.
8. (Original) The guide device of claim 1, wherein the at least one alignment element comprises at least one tab that extends distally from the guide member and that is adapted to interact with an edge of a spinal fixation element, and at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal fixation element.
9. (Original) The guide device of claim 1, wherein the at least one alignment element comprises an alignment tab that extends distally from a distal surface of the guide member and that is adapted to be disposed within a corresponding slot formed in a spinal fixation element.
10. (Original) The guide device of claim 1, wherein the at least one alignment element is adapted to prevent rotation between the guide member and a spinal fixation element when the guide member is mated to the spinal fixation element.
11. (Withdrawn) The guide device of claim 10, wherein the at least one alignment element comprises an oval protrusion that extends distally from a distal end of the guide member.
12. (Original) The guide device of claim 1, wherein the guide member has a substantially rectangular, elongate shape and the first and second pathways extend therethrough in a substantially proximal-distal direction.

13. (Original) The guide device of claim 12, wherein the guide member includes opposed superior and inferior sides and opposed transverse sides, the transverse sides having a width that is less than a width of the superior and inferior sides.
14. (Original) The guide device of claim 13, wherein the at least one alignment element comprises a first alignment tab that extends distally from the superior side of the guide member and a second alignment tab that extends distally from the inferior side of the guide member.
15. (Original) The guide device of claim 14, wherein at least one of the tabs is configured to interact with a graft window formed in a spinal fixation element.
16. (Original) The guide device of claim 13, wherein the at least one alignment element comprises first and second alignment tabs that extend distally from opposed transverse sides of the guide member.
17. (Original) The guide device of claim 1, wherein a distal surface of the guide member has a shape that conforms to the shape of a spinal fixation element.
18. (Original) The guide device of claim 1, wherein the first and second pathways are positioned at an angle with respect to one another.
19. (Original) The guide device of claim 1, wherein the first and second pathways are defined by opposed, substantially semi-cylindrical sidewalls.
20. (Cancelled).
21. (Original) The guide device of claim 1, further comprising at least one cut-out portion formed in the guide member.
22. (Original) The guide device of claim 21, wherein the guide member includes opposed superior and inferior sidewalls and opposed lateral sidewalls extending between the superior and inferior sidewalls, and wherein the at least one cut-out portion is formed in one of the superior and

inferior sidewalls.

23. (Original) The guide device of claim 22, wherein the at least one cut-out portion extends in a proximal-distal direction at a location that is substantially between the first and second pathways.

24. (Previously Presented) The guide device of claim 22, wherein the guide member includes opposed cut-out portions formed in the superior and inferior sidewalls, and wherein the cut-out portion in the superior sidewall extends between proximal and distal ends of the guide member, and the cut-out portion in the inferior sidewall extends from the distal end of the guide member and terminates distal to the proximal end of the guide member.

25-26. (Cancelled).

27. (Withdrawn) The guide device of claim 1, wherein the at least one alignment element is formed on a support member that is coupled to the distal end of the elongate shaft, and the at least one alignment element is adapted to removably engage a spinal fixation element.

28. (Withdrawn) The guide device of claim 27, wherein the guide member is slidably movable along the support member such that a position of the guide member with respect to a spinal fixation element engaged by the support member is adjustable.

29. (Withdrawn) The guide device of claim 28, further comprising an engagement mechanism formed on [[a]]the distal end of the elongate shaft and adapted to releasably engage the support member such that the position of the guide member can be temporarily fixed.

30. (Withdrawn) The guide device of claim 29, further comprising a trigger mechanism formed on the proximal end of the elongate shaft and coupled to the engagement mechanism for moving the engagement mechanism between an engaged position, wherein the guide member is fixed at a desired position, and a released position, wherein the guide member is slidably movable along the support member.

31. (Withdrawn) The guide device of claim 27, wherein the support member is arch-shaped and the at least one alignment element comprises first and second substantially concave grooves formed on opposed inner surfaces of the support member.

32. (Withdrawn) The guide device of claim 1, wherein the at least one alignment element is adapted to loosely interact with a spinal fixation element such that the guide member can pivot with respect to the spinal fixation element.

33. (Withdrawn) The guide device of claim 1, wherein the first and second pathways have an adjustable length.

34. (Cancelled).

35. (Previously Presented) A guide device for use with a spinal fixation element having at least one thru bore formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end, the proximal end of the shaft being positioned at an angle with respect to the distal end of the shaft; and

a guide member coupled to the distal end of the elongate shaft and including opposed first and second pathways formed therein at least partially in communication with one another and extending therethrough, the distal end of the elongate member being offset from the first and second pathways; and

at least one alignment tab extending distally from the guide member, the alignment element being adapted to provide a sliding interference fit with a spinal fixation element to position the guide member with respect to the spinal fixation element such that the first and second pathways in the guide member are aligned with at least one corresponding thru bore formed in the spinal fixation element.

36. (Original) The guide device of claim 35, wherein the guide member includes first and second opposed alignment tabs extending distally therefrom.

37. (Original) The guide device of claim 36, wherein the first and second alignment tabs are substantially parallel to one another.

38. (Original) The guide device of claim 36, wherein at least one of the first and second alignment tabs is configured to interact with a graft window formed in a spinal fixation element.

39. (Previously Presented) The guide device of claim 36, wherein the first and second opposed alignment tabs extend from opposed outer edges of the guide member at positions that are substantially between the first and second pathways.

40. (Previously Presented) The guide device of claim 36, wherein the first and second opposed alignment tabs extend from opposed outer edges of opposed ends of the guide member such that the first and second pathways are positioned between the first and second alignment tabs.

41-64. (Cancelled).

65. (Previously Presented) A guide device for use with a spinal fixation element having at least one thru bore formed therein, the guide device comprising:

an elongate shaft having proximal and distal ends, the proximal end of the shaft being positioned at an angle with respect to the distal end of the shaft; and

a guide member coupled to the distal end of the elongate shaft, the guide member being in the form of a substantially hollow housing having first and second pathways extending therethrough between proximal and distal ends thereof, the first and second pathways being at least partially in communication with one another, wherein the distal end of the elongate shaft is offset from the first and second pathways.

66. (Original) The device of claim 65, wherein the first and second pathways comprise opposed, substantially semi-cylindrical pathways formed within the hollow housing.

67. (Original) The device of claim 65, wherein at least a portion of each pathway is defined by a substantially elongate, semi-cylindrical sidewall of the housing.

68. (Original) The device of claim 67, wherein a distal end of each semi-cylindrical sidewall extends distally beyond a distal end of the guide member to form opposed tabs that are adapted to



seat a spinal fixation element therebetween.

69. (Original) The device of claim 68, wherein each tab has a substantially concave inner surface that is adapted to match the contour of a substantially concave outer surface formed around a perimeter of a spinal fixation element.

70. (Original) The device of claim 65, further comprising at least one cut-out portion formed in the housing between the first and second pathways.

71. (Original) The device of claim 70, wherein the housing includes opposed first and second cut-out portions extending in a proximal-distal direction, and formed substantially between the first and second pathways.

72. (Original) The device of claim 71, wherein the first cut-out portion extends from the distal end of the housing to the proximal end of the housing, and wherein the second cut-out portion extends from the distal end of the housing and terminates distal to the proximal end of the housing.

73. (Previously Presented) A guide device for use with a spinal fixation element, the guide device comprising:

an elongate shaft having proximal and distal ends, the proximal end of the shaft being positioned at an angle with respect to the distal end of the shaft; and

a guide member coupled to the distal end of the elongate shaft and adapted to be juxtaposed on a spinal fixation element having first and second thru bores formed therein, the guide member including a first substantially C-shaped lateral sidewall for guiding implants, tools, and devices through the first thru bore in the spinal fixation element, and a second, opposed substantially C-shaped lateral sidewall for guiding implants, tools, and devices through the second thru bore in the spinal fixation element.

74. (Previously Presented) A guide device for use with a spinal fixation element having at least one pair of thru bores formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end, the proximal end of the shaft being positioned at an angle with respect to the distal end of the shaft;

a guide member coupled to the distal end of the elongate shaft and including first and second pathways extending therethrough in fixed relation to one another, and opposed superior and inferior sidewalls, opposed lateral sidewalls extending between the superior and inferior sidewalls, and opposed cut-out portions formed in the superior and inferior sidewalls, wherein the cut-out portion in the superior sidewall extends between proximal and distal ends of the guide member, and the cut-out portion in the inferior sidewall extends from the distal end of the guide member and terminates distal to the proximal end of the guide member; and

at least one alignment element positioned distal of the guide member, the at least one alignment element being adapted to interact with a spinal fixation element to position the guide member with respect to the spinal fixation element such that the first and second pathways in the guide member are aligned with a pair of corresponding thru bores formed in the spinal fixation element.

1615310.1